Reviewer’s report

Title: Effects of home-based play-assisted stimulation on developmental performances of children living in extreme poverty: a randomized single-blind controlled trial

Version: 0 Date: 02 May 2017

Reviewer: Sara B. DeMauro

Reviewer's report:

The authors present an interesting study of an intensive home-based play intervention for young children in foster care and extreme poverty. In general, this is a vulnerable population deserving of study.

Specific comments:

Abstract

Background, first sentence - would say "are at high risk for" developmental problems - as the sentence stands now it appears that ALL children have problems, which couldn't be true.

Methods - spelling error in "trial"; please describe duration and intensity of the intervention.

Results - please provide the most important data/outcomes with measures of statistical significance

Background

Background is generally written well and contains appropriate references. However, lines 42-49 on page 3 are confusing. Does this refer to children in foster families and if so, please provide the references and results of prior studies in this area, because this is the focus of the current study.

Methods

Page 5 lines 1-3 - if age is an inclusion criterion it is not also an exclusion criterion; please delete.
Sample size - please further explain the difference in developmental outcome that was used to power the study. From what measure is this derived and is this a clinically significant difference? Why did the authors power the study based on this particular difference?

Delete page 5 lines 39-41 "i.e...... The blinding was evaluated to be successful." One should not evaluate whether blinding is successful in general; further the authors don't describe how they came to this conclusion so it is best to eliminate.

In general, there is a lot of discussion about "mothers" including birth order, mothers income, number of people in the home. Throughout please describe if these are birth mothers or foster mothers. It is hard to understand how birth order in the biologic family matters if the child is in foster care throughout the study. Please provide this clarification for all maternal and family variables that are included in table 1.

How did the investigators ensure that there was no contamination between intervention and control families.

Page 6, line 54 why do you say that the ASQ is unpublished? In addition please clarify - this is believed to have a higher rate of detection as compared to what?

How could the nurses doing the assessment be blinded to study group if the families in the intervention group were given lots of developmentally appropriate toys.

Results

Please provide the average number of sessions provided to each participant? surely some were cancelled or missed. this is an important measure of feasibility and success of delivering the intervention.

Page 9 line 25 says 60% but the table says 59%.

Was this study IRB approved and was consent obtained? If so, from whom?

Discussion

Please discuss the feasibility of scaling this up given the cost of the materials (can this be estimated for the reader) and the intensity of the intervention in a resource limited area?

A major limitation is that mothers completed the ASQ-SE and it is possible that the intervention increased maternal sensitivity to the child's social emotional needs. Mothers were not blinded and thus completion of this measure by unblinded mothers could be very biased. This is important because the strongest signal is in the social-emotional findings.
Page 14 lines 7-13 "average improvements"----- this sentence is confusing; please rewrite and clarify your meaning.

First paragraph of discussion, particularly page 14 lines 22-24 it is hard to determine whether authors are referring to their own work or prior work in this area.

Please differentiate between normal expected trajectories of change in the developmental measures used in this study and the trajectories of the control and intervention groups in this study.

Conclusion:

Please rewrite final sentence because it is unclear as currently written.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

Yes

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

Yes

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

I recommend additional statistical review

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